

Notice of Allowability

Application No.

09/980,772

Examiner

Deborah Crouch

Applicant(s)

BRANDON ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to June 2, 2009.
2. ☒ The allowed claim(s) is/are 1-4,6,10-13,16,17,20,22,32,34-36,41 and 43.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>8/7/09</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Deborah Crouch/
Primary Examiner, Art Unit 1632

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Claims 1-4, 6, 10-13, 16-20, 22, 31-33, 35, 36, 41 and 43 were pending in the response filed June 2, 2009.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Christopher Draco on August 7, 2009.

1. Cancel claims 18, 19, and 31, 33.
2. Replace claims 1-4, 6, 10-13, 16, 17, 20, 22, 32, 34-36, 41, and 43 as follows:

1.A method of preparing a reprogrammed diploid mammalian cell comprising providing a diploid mammalian donor nucleus derived from a somatic cell, and a mammalian recipient cell, wherein the diploid mammalian donor nucleus and the mammalian recipient cell are of the same species;

introducing the mammalian donor nucleus into the mammalian recipient cell to produce an aneuploid cell;

maintaining the aneuploid cell in a suitable environment for a period sufficient to allow the donor nucleus to be reprogrammed;

subjecting the aneuploid cell to an activation step; and

subsequent to maintaining the aneuploid cell in the suitable environment, treating said reprogrammed aneuploid cell so as to generate a reprogrammed diploid mammalian cell from said reprogrammed aneuploid cell by removal or destruction of the

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mammalian recipient cell nucleus, pronucleus, metaphase plate, chromatin, chromosomes or nuclear DNA from said reprogrammed aneuploid cell.

2. A method according to Claim 1, wherein the mammalian recipient cell is an oocyte, zygote, or embryonic blastomere.

3. A method according to Claim 2, wherein the oocyte is a metaphase II oocyte.

4. A method according to Claim 44, wherein the mammalian recipient cell is an embryonic stem cell, embryonic germ cell, primordial germ cell, or embryonal carcinoma cell.

6. A method according to Claim 1, wherein the mammalian donor nucleus is a nucleus derived from a cumulus cell.

10. A method according to Claim 1, wherein the mammalian donor nucleus is transferred to the recipient cell by piezo-assisted micromanipulation.

11. A method according to Claim 1, wherein nucleus or nuclear DNA of the mammalian recipient cell is removed or destroyed prior to division of the aneuploid cell.

12. A method according to Claim 1, wherein the mammalian donor cell nucleus is reprogrammed to an embryonic cell nucleus.

13. A method according to Claim 12, wherein the reprogrammed mammalian cell nucleus forms a mammalian embryo containing embryonic cells.

16. A method of preparing a reprogrammed genetically modified diploid mammalian cell comprising

providing a genetically modified diploid mammalian donor nucleus derived from a genetically modified somatic cell, and a mammalian recipient cell, wherein the

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genetically modified diploid mammalian donor nucleus and the mammalian recipient cell are of the same species;

introducing the genetically modified mammalian donor nucleus into the mammalian recipient cell to produce an aneuploid cell;

maintaining the aneuploid cell in a suitable environment for a period sufficient to allow the donor nucleus to be reprogrammed;

subjecting the aneuploid cell to an activation step; and

subsequent to maintaining the aneuploid cell in the suitable environment, treating said reprogrammed aneuploid cell so as to generate a reprogrammed genetically modified diploid mammalian cell from said reprogrammed aneuploid cell by removal or destruction of the mammalian recipient cell nucleus, pronucleus, metaphase plate, chromatin, chromosomes or nuclear DNA from said reprogrammed aneuploid cell.

17. A method of preparing a reprogrammed genetically abnormal diploid mammalian cell comprising

providing a genetically abnormal diploid mammalian donor nucleus derived from a genetically abnormal somatic cell comprising a mutation associated with a genetic disease, and a mammalian recipient cell, wherein the genetically abnormal diploid mammalian donor nucleus and the mammalian recipient cell are of the same species;

introducing the genetically abnormal mammalian donor nucleus into the mammalian recipient cell to produce an aneuploid cell;

maintaining the aneuploid cell in a suitable environment for a period sufficient to allow the donor nucleus to be reprogrammed;

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subjecting the aneuploid cell to an activation step; and
subsequent to maintaining the aneuploid cell in the suitable environment,
treating said reprogrammed aneuploid cell so as to generate a reprogrammed
genetically abnormal diploid mammalian cell from said reprogrammed aneuploid cell by
removal or destruction of the mammalian recipient cell nucleus, pronucleus, metaphase
plate, chromatin, chromosomes or nuclear DNA from said reprogrammed aneuploid cell.

20. A method of generating one of a group consisting of a cell and cell line from
a reprogrammed diploid mammalian cell, comprising:

(a) preparing a reprogrammed diploid mammalian cell by providing:
providing a diploid mammalian donor nucleus derived from a somatic cell, and a
mammalian recipient cell, wherein the diploid mammalian donor nucleus and the
mammalian recipient cell are of the same species;

introducing the mammalian donor nucleus into the mammalian recipient cell to
produce an aneuploid cell;

maintaining the aneuploid cell in a suitable environment for a period sufficient to
allow the donor nucleus to be reprogrammed;

subjecting the aneuploid cell to an activation step; and
subsequent to maintaining the aneuploid cell in the suitable environment,
treating said reprogrammed aneuploid cell so as to generate a reprogrammed diploid
mammalian cell from said reprogrammed aneuploid cell by removal or destruction of the
mammalian recipient cell nucleus, pronucleus, metaphase plate, chromatin,
chromosomes or nuclear DNA from said reprogrammed aneuploid cell; and

(b) generating one of a group consisting of a cell and a cell line, from said reprogrammed diploid mammalian cell.

22. A method according to Claim 20, wherein the one of a group consisting of a cell and a cell line, has been genetically modified to eliminate or reduce an undesirable activity or to provide or increase a desirable activity.

32. A method of preparing a reprogrammed mammalian cell comprising providing a diploid mammalian donor nucleus derived from a somatic cell, an exogenous nucleic acid molecule and a mammalian recipient cell, wherein the genetically modified diploid mammalian donor nucleus and the mammalian recipient cell are of the same species;

introducing the mammalian donor nucleus and exogenous nucleic acid molecule into the mammalian recipient cell to produce an aneuploid cell;

maintaining the aneuploid cell in a suitable environment for a period sufficient to allow the donor nucleus to be reprogrammed;

subjecting the aneuploid cell to an activation step; and

subsequent to maintaining the aneuploid cell in the suitable environment, treating said reprogrammed aneuploid cell so as to generate a reprogrammed diploid mammalian cell comprising an exogenous nucleic acid sequence from said reprogrammed aneuploid cell by removal or destruction of the mammalian recipient cell nucleus, pronucleus, metaphase plate, chromatin, chromosomes or nuclear DNA from said reprogrammed aneuploid cell.

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34. A method of preparing a reprogrammed diploid embryonic mammalian cell comprising:

providing a diploid mammalian donor nucleus derived from a somatic cell, and a mammalian recipient cell and one of a group consisting of a recipient mammalian oocyte and an embryonic cell, wherein the diploid mammalian donor nucleus and the mammalian recipient cell are of the same species;

introducing the mammalian donor cell nucleus into the mammalian recipient oocyte or embryonic cell to produce an aneuploid cell;

maintaining the aneuploid cell in a suitable environment for a period sufficient to allow the mammalian donor cell nucleus to be reprogrammed; and

subjecting the aneuploid cell to an activation step;

subsequent to maintaining the aneuploid cell in the suitable environment, treating said reprogrammed aneuploid cell so as to generate a reprogrammed diploid embryonic mammalian cell from said reprogrammed aneuploid cell by removal or destruction of the mammalian recipient cell nucleus, pronucleus, metaphase plate, chromatin, chromosomes or nuclear DNA from said reprogrammed aneuploid cell or one or more of its daughter cells.

35. A method according to claim 1, wherein the mammalian recipient cell is a human cell.

36. A method according to claim 1, wherein the mammalian recipient cell is a mouse cell.

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41. The method according to claim 1, wherein said treating comprises at least one of the group consisting of enucleation by micromanipulation, chemical microsurgery and laser microsurgery.

43. The method according to claim 34, wherein said treating comprises at least one of the group consisting of enucleation by micromanipulation, chemical microsurgery and laser microsurgery.

3. Add new claim 44.

44. A method according to claim 1, wherein the mammalian recipient cell is a pluripotent stem cell.

4. The title has been changed to --Process of mammalian cell reprogramming through production of a heterokaryon--.

The following is an examiner's statement of reasons for allowance: The restriction requirement mailed March 16, 2005 has been reviewed. Claims 16, 17 and 32 have been combined with group I and found allowable. Thus, the restriction requirement regarding claims 16, 17 and 32 has been withdrawn. The remaining groups indicated in the restriction requirement are maintained.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632